Remarks/Arguments:

The Office Action rejects claims 1-8 under 35 U.S.C. §103(a) on the basis of a primary citation to US-2002/0123798 (Burgermeister) in view of a secondary citation to US-2003/0124279 (Sridharan et al.).

Before addressing the contentions cited to Burgermeister and Sridrahan et al., Applicant considers it useful to first briefly discuss the invention in general. The invention relates to auxetic tubular liners – that is tubular liners that have a negative Poisson's ratio, and so when they are stretched, become thicker in the direction lateral to the direction of elongation.

A particular advantage of the tubular liners of the present invention is that they are synclastic and highly flexible by virtue of their being auxetic, yet, for example, under typical in vivo conditions provide increased counteraction upon compression (specification page 5, lines 16-19). Thus, the tubular liners of the present invention allow, for example, the minimisation of contact stress between a stent and diseased tissue by providing a support structure (the stent) which allows the vessel to conform to its natural flexibility, and further provide a less invasive route to dilation than prior art means (specification page 9, lines 5-9).

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Independent claim 1 has in view of the specification been amended, in order to anticipate aspects of disclosure and or teaching that the Office Action contends in relation to Burgermeister, Fig.'s 9 and 10, and to avoid any ambiguity in the meaning of "auxetic material", despite that the specification clarifies that "auxetic material" may have a macroscopic or microscopic meaning (specification, page 2, lines 4-5).

Independent (currently amended) claim 1 and (previously presented) claims 2-4 recite, inter alia, a tubular liner comprising an auxetic plurality of adjacent polygons, said adjacent polygons connected symmetrically by a common element.

Applicant respectfully submits that neither Burgermeister nor Sridrahan et al. discloses at least the aforementioned feature of independent (currently amended) claim 1 and (previously presented) claims 1-4. In particular, it is submitted that the primary citation to Burgermeister does not disclose the claimed tubular liner, nor does the secondary citation to Sridrahan et al. remedy the conceded deficiency in the primary citation to Burgermeister. Accordingly, without conceding the propriety of the asserted combination, the asserted combination of Burgermeister and Sridrahan et al. is likewise deficient, even in view of the knowledge of one of ordinary skill in the art.

The Office Action concedes that Burgermeister does not explicitly disclose that the connecting members may be affixed exactly at the inner vertices (Office Action, page 4, lines 12-13).

Nonetheless, the Office Action contends that Burgermeister teaches that "*the nearer the connecting elements are attached to the inner vertices, the more the stent will increase in length as it radially expands*", and that "*It would have been obvious to one of ordinary skill in the art at the time of the invention to affix the connecting members to the inner vertices in order to maximize the lengthening property as taught by Burgermeister. Thus, Burgermeister teaches a tubular liner comprising a plurality of*

adjacent radial loops wherein each loop comprises a plurality of interconnected hexagons as claimed in claims 2-4." (Office Action, page 4, lines 13-14; page 5 lines 1-5). This contention is respectfully traversed.

Burgermeister expressly teaches a preferred embodiment of a stent to provide, inter alia, reduction of foreshortening of the stent mechanism [upon expansion] (Burgermeister, Abstract, lines 2-3, and [**0012**]). Moreover, all embodiments in Burgermeister with connecting elements affixed to inner vertices (that is, Burgermeister, Fig.'s 1A, 2A and 3A) cannot lead to stent lengthening upon radial expansion as a direct result of these elements being attached to inner vertices.

Furthermore, Burgermeister teaches that the "*"wavy" strut configuration*" (as for example shown in Burgermeister, Fig. 10) facilitates "*reduced strain upon expansion*" when "*attaching the flexible connectors at or near a strut mid-point*", "*due to the strut* [the connecting element] *itself contributing to a portion of the expansion*" ([**0021**]). In other words, following the definition of strain, the "*"wavy" strut configuration*" is stated to facilitate either reduced foreshortening or reduced lengthening upon stent expansion. Although it is not clear how a "*"wavy" strut configuration*" can facilitate reduced lengthening upon expansion when "*contributing to a portion of the expansion*", the possibility of adding length as indicated by Burgermeister in Fig. 10 is therefore expected to be at least partly caused by the "*"wavy" strut configuration*" contributing to stent expansion.

Consequently, the person of ordinary skill would have no motivation to affix the connecting members to the inner vertices, in order to maximize the lengthening property.

Sridrahan et al. teaches that "*Materials with node and fibril structures that can be rendered auxetic, i.e., having a negative Poisson's ratio, with appropriate processing are particularly suitable for this application* [that is angioplasty balloons]" ([**0007**], lines 13-16). Thus, Sridrahan et al. does not provide a disclosure that remedies the aforementioned, conceded deficiency in the primary citation to Burgermeister.

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Accordingly, favourable reconsideration and withdrawal of the rejection of claims 1-4 under 35 U.S.C. §103(a) are respectfully requested.

In regard to claim 5, the Office Action argues that:

"*..., it is not clear whether claim 5 recites that the elongate strips are oriented along the longitudinal axis or, alternatively, that the interconnected hexagons are oriented along the longitudinal axis.*"

Claim 5 recites "*...a plurality of longitudinally elongate strips of interconnected hexagons oriented along said longitudinal axis of said tubular liner,...*". The elongate strips that are comprised of interconnected hexagons are according to this claim aligned in the longitudinal axis by definition ("*longitudinally elongate strips*"), therefore the hexagons must also be aligned in this axis. The orientation of the individual hexagons that form part of these longitudinal strips with respect to the main (longitudinal) axis is pointed out further in claim 5 by reciting that "*said first and second sides of said hexagons* [that is the connecting elements between the zigzags] *being oriented perpendicular to said longitudinal axis;...*".

In regard to claims 5-8 the Office Action on page 5, lines 9-15 contends that:

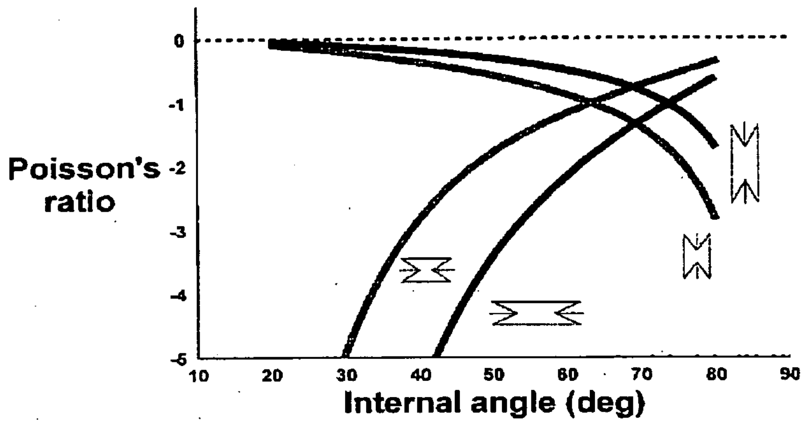
"*It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burgermeister by orienting the bands of interconnected hexagons longitudinally to form elongated strips since such a modification would have merely required a rearrangement of the existing device and would not have produced unexpected results. Additionally, such an arrangement would also have be*[en] *useful in reducing foreshortening of the stent during radial expansion.*"

The current specification recites on page 7, lines 16-18 that "*Properties of the tubular liner, including the extent of its auxetic nature, can be modified depending upon the exact construction of the inverted hexagons.*". For example, page 8, lines 61-10 states that "*As compression takes place, the tubular liner becomes more rigid in its structure at the point or region of compression and more resistant to deformation, the degree of which is controlled by the structure of the tubular liner (eg first and second sides perpendicular to the longitudinal axis, or parallel to it). For example, increasing the length of the connecting members increases the flexibility of the tubular liner.*"

As a second example, the specification on page 9, lines 10-15 states that "*As well as the above tubular liner structures using inverted hexagons (in which the first and second parallel sides are oriented in the longitudinal axis of the tubular liner), structures can also be made in which the first and second parallel sides are oriented perpendicular to the longitudinal axis of the tubular liner. These structures whilst also being auxetic can be manufactured such that they are capable of little radial compression or expansion, yet are capable of substantial longitudinal compression or expansion.*"

Further to these examples mentioned in the present application, Fig. 1 of this paper shows a graph of Poisson's ratio against internal angle between the connecting elements and zigzag struts, for four stents and in function of (i) length of the connecting member and (ii) their orientation with respect to the main axis (parallel or perpendicular to the longitudinal axis). Reference point is an internal angle of 45° at which the stents are fully relaxed. At angles greater than 45° the stent is being expanded, whereas at angles below 45° the stent is being compressed. At 45° all four stents have approximately the same diameter and stent length, see Table 1 of this paper with details of dimensions used to construct the graph. Poisson's ratio is defined as minus the change in diameter divided by change in length; radial expansion of the auxetic tubular liner leads to a positive change in diameter and length, which results in a negative Poisson's ratio.

Fig. 1: The effect of hexagon orientation and length of the connecting member on Poisson's ratio for a given stent size defined at an internal angle of 45° (between the connecting members and zigzag struts). The main axis of the stent is taken parallel to the X-axis.



As Fig. 1 above shows, in the case of aligning connecting members parallel to the longitudinal axis (see lower two curves) the Poisson's ratio is more negative (indicating increased auxetic behaviour) the longer the connecting member. However, when the connecting members are aligned perpendicular to the longitudinal axis, the opposite holds true, that is Poisson's ratio is more negative when the parallel connecting members are shorter. Moreover, the upper two curves in Fig. 1 illustrate that, reoriented as such (that is first and second hexagon sides perpendicular to the longitudinal axis) the arrangement would be useful to try and reduce lengthening as opposed to reduce foreshortening during radial expansion as contended in the Office Action. Consequently, Applicant argues that the relation between hexagon orientation and Poisson's ratio (ie degree of auxetic nature) is unexpected and not obvious to the person of ordinary skill in the art.

Table 1: Data used to construct the graph presented in Fig. 1. Differences amongst the four stents between their diameter and length result because integers have to be used for number of hexagons in both the lateral and longitudinal direction.

orientation of connecting member relative to long axis	length connecting member (mm)	length zigzag strut (mm)	angle between connecting member and zigzag strut (°)	stent diameter (mm)	stent length (mm)	Poisson's ratio
perpendicular	8.0	$\sqrt{5}$	45	10.20	104.3	-0.263
perpendicular	5.0	$\sqrt{5}$	45	9.70	104.3	-0.492
parallel	8.0	$\sqrt{5}$	45	10.07	104.2	-4.120
parallel	5.0	$\sqrt{5}$	45	10.07	104.1	-2.140

Accordingly, favourable reconsideration and withdrawal of the rejection of claims 5-8 under 35 U.S.C. §103(a) are respectfully requested.

Because claim 9 which is recited in claim 10 has been withdrawn from further consideration as being drawn to a non-elected group, claim 10 has been cancelled.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Attachments:

1. PTO/SB/22 (02-09)
2. PTO-2038 (09-2006)
3. PTO/SB/81 (01-09)
4. PTO/SB/122 (11-08)